UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,699	08/05/2003	Pablo Umana	1975.0010004/TJS	5489

26111 7590 03/23/2006

STERNE, KESSLER, GOLDSTEIN & FOX PLLC
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
RIGGINS, PATRICK S	

ART UNIT	PAPER NUMBER
1633	

DATE MAILED: 03/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,699	UMANA ET AL.	
	Examiner	Art Unit	
	Patrick S. Riggins	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *7/18/05,10/12/05,12/28/05*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *109-139* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *109-139* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of amendments filed 7/18/05, 10/12/05, and 12/28/05. Claims 86-108 were canceled and claims 109-139 were added. The amendment to the specification filed 12/28/05 is acceptable and is entered.

Response to Amendment

2. The Declaration under 37 CFR 1.132 filed 7/18/05 is insufficient to overcome the rejection of claims 87-107 based upon 35 U.S.C. 112, first paragraph as set forth in the last Office action because: each piece of evidence provided in the declaration is derived from information not available as of the effective filing date of the instant application. Each of these the three cited references in the declaration disclose information regarding the antibodies of the invention wee performed after the effective filing date of the instant application and as such the information gleaned from these studies was not available to the skilled artisan at the time of the invention.

3. In this regard however, applicant's arguments, see page 19, first full paragraph of the amendment, filed 7/18/05, with respect to the lack of serum in the methods of the invention have been fully considered and are persuasive. The rejection of claims 87-108 under 35 U.S.C. 112, first paragraph has been withdrawn.

4. Applicant's arguments, see the bottom of page 22 through the top of page 25 in the amendment, filed 7/18/05, with respect to the applicability of Lifely to the instantly pending claims have been fully considered and are persuasive. The rejection of claims 86-108 under 35 U.S.C. 102 or 103 has been withdrawn.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 137 and 138 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a NEW MATTER rejection.

7. Claim 137 is drawn to the antibody of the invention wherein "at least 45% of the oligosaccharides" are complex structures. Applicant points to page 37, lines 19-21 to indicate support for this limitation. This portion of the specification fails to support the full scope of the newly entered claim. Indeed this portion of the specification teaches that "45 to 50%" is achieved. The claim encompasses an open-ended amount and as such introduces impermissible new matter, not supporter by the originally filed specification.

8. Claim 138 is drawn to the antibody of the invention wherein the antibody "exhibits at least and 80% increase in maximal ADCC activity". Applicant points to page 22, line 33 through page 23, line 11 to indicate support for this limitation. This portion of the specification teaches that "almost 80%" can be achieved. Thus claim 138 does not find support in the specification and as such introduced impermissible new matter.

9. Claims 109-139, readable on a recombinant glycoengineered antibody produced in a genus of cell types using a genus of glycosyltransferases, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

10. The description as filed only provides sufficient written support for production of antibodies with altered glycosylation that were produced in CHO cells expressing GnTIII. There is no disclosure of any other modified cell type that will lead to the production of recombinant antibodies with the characteristics of having an increased proportion of non-fucosylated oligosaccharides relative to an unmodified cell, wherein the recombinant antibody has increased c-mediated cellular cytotoxicity and increased Fc receptor binding. Indeed the mention of studies in BHK cells in Example 6 appears to be completely prophetic in nature with evidence that modified BHK cells would produce antibodies that were modified in a similar manner to modified CHO cells. Indeed, Lifely (Glycobiology 5: 813-822 (1995), of record) teaches that recombinant antibodies produced in different cell types result in antibodies having distinct glycosylation patterns and distinct levels of ADCC-induction (see particularly Figure 1 and Figure 5). Thus Lifely clearly teaches that different cells produce differentially glycosylated recombinant antibodies. There is no evidence provided in the specification that any glycosyltransferases aside from GnTIII, transfected into any cell other than CHO cells would lead to the production of antibodies having the same characteristics as those produced in CHO cells expressing exogenous GnTIII.

11. With respect to a required description of a representative number of species of multiple cell types modified with a variety of different glycosyltransferases, a review of the state of the prior art appears to indicate that glycosylation patterns due to unmodified cells and indeed the differences that could be expected with modification by different glycosyltransferases remains unclear and complex at the time the invention was made, and that further studies with evidence are necessary to investigate the functional roles of different glycosyltransferases in different cell types. It is apparent that on the basis of applicants' disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or assays and/or any other unspecified structure containing unspecified sequences that are only described by functional language, wherein the detailed and common structure of the genera of the claimed different cell types expressing different glycosyltransferases was not described; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structure(s) of component(s) that are linked in order to exhibit the disclosed biological functions as contemplated by the as-filed specification.

12. It is not sufficient to support the present claimed invention directed to antibodies produced in cells expressing different glycosyltransferases to result in antibodies with particular glycosylation patterns and activities with regard to ADCC with no common structure being claimed in the presently pending claims because disclosure of no more than that, as in the instant case, is simply a wish to know the identity of any and/or all other material(s) of agents other than those known in the prior art, as admitted by the as-filed specification, having the biological functions as contemplated by the specification and the claims. The claimed invention as a whole

is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which is not conventional in the art as of applicants effective filing date. Claiming unspecified molecular structures of antibodies produced in any cell type engineered to express any glycosyltransferase, which must possess the biological properties as contemplated by applicants' disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v. Revel*, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. V. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventors had possession of the claimed invention. (*Pfaff v. Wells Electronics, Inc.*, 48 USPQ2d 1641, 1646 (1998)).

Double Patenting

13. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

14. Claims 109, 110, 120, and 133 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 113-116 and 256-258 of copending Application No. 10/981,738, as follows: instant claims 109 and 133 over reference claims 113, 116, and 256, instant claim 110 over reference claims 114, 114, and 256, and instant claim 120 over reference claim 257. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because, in the case of instant claims 109, 110, 120, and 133, they are generic to all that is recited in the respective claims of the reference, i.e. the reference claims fall entirely within the scope of each of instant claims 109, 110, 120, and 133.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

15. Claims 109, 110, 114, 115, and 133 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 96-98, 108-111, 213, 261-263, and 273-276 and 256-258 of copending Application No. 10/761,435, as follows: instant claims 109 and 133 over reference claims 96, 98, 213, 261, and 263, instant claim 110 over reference claims 96-97, 213, and 261-262, instant claim 114 over reference claims 108, 110, 273, and 275, and instant claim 115 over reference claims 109, 111, 274, and 276. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s)

because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because, in the case of instant claims 109, 110, 114, 115, and 133, they are generic to all that is recited in the respective claims of the reference, i.e. the reference claims fall entirely within the scope of each of instant claims 109, 110, 114, 115, and 133.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 109, 114, 115, 128, and 133 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 74-85 of copending Application No. 10/633, 697, as follows: instant claims 109 and 133 over reference claims 74-83, instant claim 114 over reference claim 84, instant claim 115 over reference claim 85, and instant claim 128 over reference claims 75-83. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). Although the conflicting claims are not identical, they are not patentably distinct from each other because, in the case of instant claims 109, 114, 115, 128, and 133, they are generic to all that is recited in the respective claims of the reference, i.e. the reference claims fall entirely within the scope of each of instant claims 109, 114, 115, 128, and 133.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

17. Claims 109 and 133 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 127 of copending Application No. 10/437,388. Although the conflicting claims are not identical, they are not patentably distinct from each other because, an obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, there reference claim(s). Chapter 804 of the MPEP states,

> [t]he specification can always be used as a dictionary to learn the meaning of a term in the patent [reference] claim. In re Boylan, 392 F.2d 1017, 157 USPQ 370 (CCPA 1968). Further, those portions of the specification which provide support for the patent [reference] claims may also be examined and considered when addressing the issue of whether a claim in the application defines an obvious variation of an invention claimed in the patent [reference]. In re Vogel, 422 F.2d 438, 441-42, 164 USPQ 619, 622 (CCPA 1970). The court in Vogel recognized "that it is most difficult, if not meaningless, to try to say what is or is not an obvious variation of a claim," but that one can judge whether or not the invention claimed in an application is an obvious variation of an embodiment disclosed in the patent [reference] which provides support for the patent [reference] claim. According to the court, one must first "determine how much of the patent [reference] disclosure pertains to the invention claimed in the patent [reference]" because only "[t]his portion of the specification supports the patent [reference] claims and may be considered." The court pointed out that "this use of the disclosure in not in contravention of the cases forbidding its use as prior art, nor is it applying the patent [reference] as a reference under 35 U.S.C 103, since only the disclosure of the invention claimed in the patent [reference] may be examined."

The instant claims 109 and 133 are more narrowly drawn than reference claim 127. However, as the instant application and the reference application are both continuations of application number 09/294,584 they necessarily share the same specification. Thus the reference application necessarily teaches the additional limitation of increased Fc-mediated cellular cytotoxicity found

in instant claims 127. Thus, instant claims 86 and 108 are not patentably distinct from reference claim 127.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

18. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick S. Riggins whose telephone number is (571) 272-6102. The examiner can normally be reached on M-F 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DAVE TRONG NGUYEN
SUPERVISORY PATENT EXAMINER

Patrick Riggins, Ph.D.
Examiner
Art Unit 1633